In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS
No. 02-1648V
(To be published[1])

ALISON BUSHNELL and, DANIEL BUSHNELL, individually and as next friends of J.R.B., a minor,	*	
Petitioners,	*	Filed: June 12, 2015
v.	*	
SECRETARY OF HEALTH AND HUMAN SERVICES	*	Vaccine Act Entitlement; Causation-in-fact; Mercury; Mitochondrial Disorder; Autism Spectrum Disorder.
Respondent.	*	

Michael T. Gallagher, The Gallagher Law Firm, Houston, TX, for Petitioners.
Traci R. Patton, U.S. Department of Justice, Washington, DC, for Respondent.

DECISION

HASTINGS, *Special Master*.

This is an action in which Petitioners, Alison and Daniel Bushnell, seek an award under the National Vaccine Injury Compensation Program (hereinafter "the Program[2]), on account of their son J.R.B.'s autism spectrum disorder ("ASD"), which they believe was caused by one or more of a series of mercury-containing vaccines administered between October 6, 1998, and

[1] Because I have designated this document to be published, this document will be made available to the public unless petitioners file, within fourteen days, an objection to the disclosure of any material in this decision that would constitute "medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of privacy." *See* 42 U.S.C. § 300aa-12(d)(4)(B); Vaccine Rule 18(b).

[2] The applicable statutory provisions defining the Program are found at 42 U.S.C. § 300aa-10 *et seq.* (2006 ed.). Hereinafter, for ease of citation, all "§" references will be to 42 U.S.C. (2006 ed.).

February 1, 2000.[3] For the reasons set forth below, I conclude that Petitioners are not entitled to an award.

I

THE APPLICABLE STATUTORY SCHEME

Under the National Vaccine Injury Compensation Program, compensation awards are made to individuals who have suffered injuries after receiving vaccines. In general, to gain an award, a petitioner must make a number of factual demonstrations, including showing that an individual received a vaccination covered by the statute; received it in the United States; suffered a serious, long-standing injury; and has received no previous award or settlement on account of the injury. Finally – and the key question in most cases under the Program – the petitioner must also establish a *causal link* between the vaccination and the injury. In some cases, the petitioner may simply demonstrate the occurrence of what has been called a "Table Injury." That is, it may be shown that the vaccine recipient suffered an injury of the type enumerated in the "Vaccine Injury Table," corresponding to the vaccination in question, within an applicable time period following the vaccination also specified in the Table. If so, the Table Injury is presumed to have been caused by the vaccination, and the petitioner is automatically entitled to compensation, unless it is affirmatively shown that the injury was caused by some factor other than the vaccination. § 300aa-13(a)(1)(A); § 300 aa-11(c)(1)(C)(i); § 300aa-14(a); § 300aa-13(a)(1)(B).

In other cases, however, the vaccine recipient may have suffered an injury *not* of the type covered in the Vaccine Injury Table. In such instances, an alternative means exists to demonstrate entitlement to a Program award. That is, the petitioner may gain an award by showing that the recipient's injury was "caused-in-fact" by the vaccination in question. § 300aa-13(a)(1)(B); § 300aa-11(c)(1)(C)(ii). In such a situation, of course, the presumptions available under the Vaccine Injury Table are inoperative. The burden is on the petitioner to introduce evidence demonstrating that the vaccination actually caused the injury in question. *Althen v. HHS*, 418 F.3d 1274, 1278 (Fed. Cir. 2005); *Hines v. HHS*, 940 F.2d 1518, 1525 (Fed. Cir. 1991). The showing of "causation-in-fact" must satisfy the "preponderance of the evidence" standard, the same standard ordinarily used in tort litigation. § 300aa-13(a)(1)(A); *see also Althen*, 418 F.3d at 1279; *Hines*, 940 F.2d at 1525. Under that standard, the petitioner must show that it is "more probable than not" that the vaccination was the cause of the injury. *Althen*, 418 F.3d at 1279. The petitioner need not show that the vaccination was the sole cause or even the predominant cause of the injury or condition, but must demonstrate that the vaccination was at least a "substantial factor" in causing the condition, and was a "but for" cause. *Shyface v. HHS*, 165 F.3d 1344, 1352 (Fed. Cir. 1999). Thus, the petitioner must supply "proof of a logical sequence of cause and effect showing that the vaccination was the reason for the injury;" the logical sequence must be supported by "reputable medical or scientific explanation, *i.e.*, evidence

[3] Specifically, Petitioners' amended petition places the following vaccinations at issue in this case: DTP/DaPT administered 10/6/1998, 12/7/1998, 2/9/1999, and 2/10/2000; Hib administered 10/6/1998; 12/7/1998; OPV administered 2/7/1998 and 2/10/2000; MMR administered 8/9/99; Hep A administered 12/7/1999; Hep B administered 8/19/1998 and 10/6/1998. (*See* Amended Petition ("Am Pet")(ECF No. 18), pp. 1-2, 5; *see also* p. 8 of this Decision.)

in the form of scientific studies or expert medical testimony." *Althen*, 418 F.3d at 1278; *Grant v. HHS*, 956 F.2d 1144, 1148 (Fed. Cir. 1992).

The *Althen* court also provided additional discussion of the "causation-in-fact" standard, as follows:

> Concisely stated, Althen's burden is to show by preponderant evidence that the vaccination brought about her injury by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of proximate temporal relationship between vaccination and injury. If Althen satisfies this burden, she is "entitled to recover unless the [government] shows, also by a preponderance of the evidence, that the injury was in fact caused by factors unrelated to the vaccine."

Althen, 418 F.3d at 1278 (citations omitted). The *Althen* court noted that a petitioner need not necessarily supply evidence from *medical literature* supporting petitioner's causation contention, so long as the petitioner supplies the *medical opinion* of an expert. (*Id*. at 1279-80.) The court also indicated that, in finding causation, a Program fact-finder may rely upon "circumstantial evidence," which the court found to be consistent with the "system created by Congress, in which close calls regarding causation are resolved in favor of injured claimants." (*Id*. at 1280.)

Since *Althen*, the Federal Circuit has addressed the causation-in-fact standard in several additional rulings, which have affirmed the applicability of the *Althen* test, and afforded further instruction for resolving causation-in-fact issues. In *Capizzano v. HHS*, 440 F.3d 1317, 1326 (Fed. Cir. 2006), the court cautioned Program fact-finders against narrowly construing the second element of the *Althen* test, confirming that circumstantial evidence and medical opinion, sometimes in the form of notations of treating physicians in the vaccinee's medical records, may in a particular case be sufficient to satisfy that second element of the *Althen* test. Both *Pafford v. HHS*, 451 F.3d 1352, 1355 (Fed. Cir. 2006), and *Walther v. HHS*, 485 F.3d 1146, 1150 (Fed. Cir. 2007), discussed the issue of which party bears the burden of ruling out potential non-vaccine causes. *DeBazan v. HHS*, 539 F.3d 1347 (Fed. Cir. 2008), concerned an issue of what evidence the special master may consider in deciding the initial question of whether the petitioner has met her causation burden. The issue of the temporal relationship between vaccination and the onset of an alleged injury was further discussed in *Locane v. HHS*, 685 F.3d 1375 (Fed. Cir. 2012), and *W.C. v. HHS*, 704 F.3d 1352 (Fed. Cir. 2013). *Moberly v. HHS*, 592 F.3d 1315 (Fed. Cir. 2010), concluded that the "preponderance of the evidence" standard that applies to Vaccine Act cases is the same as the standard used in traditional tort cases, so that *conclusive* proof involving medical literature or epidemiology is *not* needed, but demonstration of causation must be more than "plausible" or "possible." Both *Andreu v. HHS*, 569 F.3d 1367 (Fed. Cir. 2009), and *Porter v. HHS*, 663 F.3d 1242 (Fed. Cir. 2011), considered when a determination concerning an expert's credibility may reasonably affect the outcome of a causation inquiry. *Broekelschen v. HHS*, 618 F.3d 1339 (Fed. Cir. 2010), found that it was appropriate for a special master to determine the reliability of a diagnosis before analyzing the likelihood of vaccine causation. *Lombardi v. HHS*, 656 F.3d 1343 (Fed. Cir. 2011), and *Hibbard v. HHS*, 698 F.3d 1355 (Fed. Cir. 2012), both again explored the importance of assessing the accuracy of the diagnosis that supports a claimant's

theory of causation. *Doe 11* v. HHS, 601 F.3d 1349 (Fed.Cir. 2010) and *Deribeaux v. HHS*, 717 F.3d 1363 (Fed. Cir. 2013), both discuss the burden of proof necessary to establish that a "factor unrelated" to a vaccine may have caused the alleged injury.

Another important aspect of the causation-in-fact case law under the Program concerns the factors that a special master should consider in evaluating the reliability of expert testimony and other scientific evidence relating to causation issues. In *Daubert v. Merrell Dow Pharmaceuticals, Inc*., 509 U.S. 579 (1993), the Supreme Court listed certain factors that federal trial courts should utilize in evaluating proposed expert testimony concerning scientific issues. In *Terran v. HHS*, 195 F.3d 1302, 1316 (Fed. Cir. 1999), the Federal Circuit ruled that it is appropriate for special masters to utilize *Daubert*'s factors as a framework for evaluating the reliability of causation-in-fact theories presented in Program cases.

II

THE OMNIBUS AUTISM PROCEEDING ("OAP")

This case is one of more than 5,400 cases filed under the Program in which petitioners alleged that conditions known as "autism" or "autism spectrum disorders" ("ASD") were caused by one or more vaccinations. A special proceeding known as the Omnibus Autism Proceeding ("OAP") was developed to manage these cases within the Office of Special Masters ("OSM"). A detailed history of the controversy regarding vaccines and autism, along with a history of the development of the OAP, was set forth in the six entitlement decisions issued by three special masters as "test cases" for two theories of causation litigated in the OAP (see cases cited below), and will only be summarized here.

A group called the Petitioners' Steering Committee ("PSC") was formed in 2002 by the many attorneys who represented Vaccine Act petitioners who raised autism-related claims. About 180 attorneys participated in the PSC. Their responsibility was to develop any available evidence indicating that vaccines could contribute to causing autism, and eventually present that evidence in a series of "test cases," exploring the issue of whether vaccines could cause autism, and, if so, in what circumstances. Ultimately, the PSC selected groups of attorneys to present evidence in two different sets of "test cases" during many weeks of trial in 2007 and 2008. In the six test cases, the PSC presented two separate theories concerning the causation of ASDs. The first theory alleged that the *measles* portion of the measles, mumps, rubella ("MMR") vaccine could cause ASDs. That theory was presented in three separate Program test cases during several weeks of trial in 2007. The second theory alleged that *vaccines containing thimerosal*, a form of mercury, could directly affect an infant's brain, thereby substantially contributing to the causation of ASD. That theory was presented in three additional test cases during several weeks of trial in 2008.

Decisions in each of the three test cases pertaining to the PSC's *first* theory rejected the petitioners' causation theories. *Cedillo v. HHS*, No. 98-916V, 2009 WL 331968 (Fed. Cl. Spec. Mstr. Feb. 12, 2009), *aff'd*, 89 Fed. Cl. 158 (2009), *aff'd*, 617 F.3d 1328 (Fed. Cir. 2010); *Hazlehurst v. HHS*, No. 03-654V, 2009 WL 332306 (Fed. Cl. Spec. Mstr. Feb. 12, 2009), *aff'd*, 88 Fed. Cl. 473 (2009), *aff'd*, 604 F.3d 1343 (Fed. Cir. 2010); *Snyder v. HHS*, No. 01-162V,

2009 WL 332044 (Fed. Cl. Spec. Mstr. Feb. 12, 2009), *aff'd*, 88 Fed. Cl. 706 (2009).[4] Decisions in each of the three "test cases" pertaining to the PSC's *second* theory also rejected the petitioners' causation theories, and the petitioners in each of those three cases chose not to appeal. *Dwyer v. HHS*, No. 03-1202V, 2010 WL 892250 (Fed. Cl. Spec. Mstr. Mar. 12, 2010); *King v. HHS*, No. 03-584V, 2010 WL 892296 (Fed. Cl. Spec. Mstr. Mar 12, 2010); *Mead v. HHS*, No. 03-215V, 2010 WL 892248 (Fed. Cl. Spec. Mstr. Mar. 12, 2010).

The "test case" decisions were comprehensive, analyzing in detail all of the evidence presented on both sides. The three test case decisions concerning the PSC's *first* theory (concerning the MMR vaccine) totaled more than 600 pages of detailed analysis, and were solidly affirmed in many more pages of analysis in three different rulings by three different judges of the United States Court of Federal Claims, and in two rulings by two separate panels of the United States Court of Appeals for the Federal Circuit. The three special master decisions concerning the PSC's *second* theory (concerning vaccinations containing the preservative "thimerosal") were similarly comprehensive.

All told, the 11 lengthy written rulings by the special masters, the judges of the U.S. Court of Federal Claims, and the panels of the U.S. Court of Appeals for the Federal Circuit *unanimously rejected* the petitioners' claims, finding no persuasive evidence that either the MMR vaccine or thimerosal-containing vaccines could contribute in any way to the causation of autism.

Thus, the proceedings in the six "test cases" concluded in 2010. Thereafter, the Petitioners in this case, and the petitioners in other cases within the OAP, were instructed to decide how to proceed with their own claims. The vast majority of those autism petitioners elected either to withdraw their claims or, more commonly, to request that the special master presiding over their case decide their case on the written record, uniformly resulting in a decision rejecting the petitioner's claim for lack of support. However, a small minority of the autism petitioners have elected to continue to pursue their cases, seeking other causation theories and/or other expert witnesses. A few such cases have gone to trial before a special master, and in the cases of this type decided thus far, all have resulted in rejection of petitioners' claims that vaccines played a role in causing their child's autism. *See, e.g.*, *Blake v. HHS*, No. 03-31V, 2014 WL 2769979 (Fed. Cl. Spec. Mstr. Vowell May 21, 2014) (autism not caused by MMR vaccination); *Henderson v. HHS*, No. 09-616V, 2012 WL 5194060 (Fed. Cl. Spec. Mstr. Vowell Sept. 28, 2012) (autism not caused by pneumococcal vaccination); *Franklin v. HHS*, No. 99-855V, 2013 WL 3755954 (Fed. Cl. Spec. Mstr. Hastings May 16, 2013) (MMR and other vaccines found not to contribute to autism); *Coombs v. HHS*, No. 08-818V, 2014 WL 1677584 (Fed. Cl. Spec. Mstr. Hastings Apr. 8, 2014) (autism not caused by MMR or Varivax vaccines); *Long v. HHS*, No. 08-792V, 2015 WL 1011740 (Fed. Cl. Spec. Mstr. Hastings Feb. 9, 2015) (autism not caused by influenza vaccine); *Brook v. HHS*, No. 04-405V (Fed. Cl. Spec. Mstr. Hastings May 14, 2015) (autism not caused by MMR/Varivax vaccines). In addition, some causation autism claims have been rejected without trial, at times over the petitioner's objection, in light of the failure of the petitioner to file plausible proof of vaccine-causation. *See, e.g.*, *Waddell v. HHS*, No. 10-316V, 2012 WL 4829291 (Fed. Cl. Spec. Mstr. Campbell-Smith Sept.

[4] The petitioners in *Snyder* did not appeal the ruling to the U.S. Court of Appeals for the Federal Circuit.

19, 2012) (autism not caused by MMR vaccination); *Geppert v. HHS*, No. 00-286V, 2013 WL 2500852 (Fed. Cl. Spec. Mstr. Vowell Sept. 6, 2012); *Fesanco v. HHS*, No. 02-1770, 2010 WL 4955721 (Fed. Cl. Spec. Mstr. Hastings Nov. 9, 2010); *Fresco v. HHS*, No. 06-469V, 2013 WL 364723 (Fed. Cl. Spec. Mstr. Vowell Jan. 7, 2013); *Pietrucha v. HHS*, No. 00-269V, 2014 WL 4538058 (Fed. Cl. Spec. Mstr. Hastings Aug. 22, 2014). Judges of this court have affirmed the practice of dismissal without trial in such a case. *E.g., Fesanco v. HHS*, 99 Fed. Cl. 28 (2011) (Judge Braden).

In none of the rulings since the test cases has a special master or judge found any merit in an allegation that any vaccine can contribute to causing autism.

III

PROCEDURAL HISTORY

On November 20, 2002, Petitioners filed a petition (styled as a "complaint") alleging that their son, J.R.B., "is a minor who received a series of mercury-containing vaccines and who subsequently demonstrated developmental problems." (*See* Petition ("Pet."), p. 1.) Petitioners further alleged that J.R.B. "suffers from mercury poisoning and not from any condition associated with any therapeutic component in any of the vaccines listed." (*Id*., p. 5.) The case was assigned to me on November 20, 2002. (*See* Notice of Assignment, Filed November 20, 2002 (ECF No. 2).)

On December 9, 2002, I issued a "Notice Regarding "Omnibus Autism Proceeding" in a number of cases, including this one. (*See* Notice, filed December 9, 2002 (ECF No. 3).) In my notice, I indicated that based on the allegations of the petition, the Petitioners would be permitted to delay the filing of medical records in the case until I resolved the general "causation" issues to be addressed in the OAP. (*Id.*, p. 1.) Those issues and the course of the OAP are discussed in greater detail in Section II, above.

On July 15, 2008, I issued an order indicating that petitioners with cases delayed pending the OAP, such as this case, would be permitted to complete the record of their individual cases in two phases – the first phase being limited to records necessary to determine whether the statute of limitations had been met, and the second phase consisting of all remaining records necessary to complete the record of the case. (*See* Order, filed July 15, 2008 (ECF No. 11), pp. 1-4.) Petitioners were also advised that they retained the option to file a complete record immediately. (*Id.*, p. 3, fn. 3; p. 5, fn. 4.) Petitioners were given 90 days to comply, and Respondent was ordered to file a statement within 45 days thereafter indicating whether this case should proceed in the OAP. (*Id*., p. 5.)

Petitioners filed medical records designated as Exhibits 1-6, via a compact disc, on October 9, 2008. (*See* Notice of Filing, October 8, 2008 (ECF No. 12).) On October 17, 2008, Petitioners filed a Statement of Compliance, indicating that they believed they had satisfied both phases of medical records production required by my order of July 15, 2008. (*See* Statement of Completion, filed October 17, 2008 (ECF No. 13).)

Respondent filed the required statement regarding continuation in the OAP on November 25, 2008. (*See* Notice, filed November 25, 2008 (ECF No. 15).) Respondent indicated that

further factual development was necessary to determine whether the statute of limitations had been met. (*Id*., p. 4, fn. 1.)

On November 26, 2008, Petitioners filed a Statement of Completion, indicating that they had filed "all records known to be available to them." (*See* Statement of Completion, filed November 26, 2008 (ECF No. 16).)[5]

Subsequently, on November 8, 2012, I issued an order in this case updating Petitioners on the outcome of the six OAP test cases, including appeals. (*See* Order, filed November 8, 2012, ECF No. 17, pp. 1-2.) Although I advised Petitioners that the OAP test cases are not binding, I noted that the test cases indicate that their claim was unlikely to be successful absent different evidence or theories not presented in the test cases. (*Id*., p. 2.) Petitioners were allowed 30 days to inform the court whether they intended to proceed with this claim or to exit the Vaccine Program. (*Id*.)

Thereafter, on December 7, 2012, Petitioners filed an amended petition. In their amended petition, Petitioners alleged that J.R.B. was diagnosed as having a "mitochondrial disorder" on March 18, 2009 (Am. Pet., p. 3), and that "his mitochondrial disorder caused an "enzyme deficiency." (*Id.*, p. 5). Petitioners alleged that J.R.B.'s enzyme deficiency led to an "accumulation of Thimerosal contained in the vaccines he was administered," and that such thimerosal accumulation led to his ASD. (*Id*., p. 5.) Accompanying the amended petition, Petitioners filed Exhibit 7, consisting of medical records pertaining to J.R.B.'s mitochondrial evaluations. (*See* Ex. 7 (ECF No. 18-1).)

Thereafter, on January 16, 2013, Petitioners were ordered to file an expert report supporting the causation theory alleged by their amended petition. (ECF No. 19.) In a series of status reports, Petitioners indicated that further testing was pending relating to J.R.B.'s mitochondrial disorder and that additional medical records would be produced. (See ECF Nos. 20-22.) On August 16, 2013, Petitioners filed further medical records identified as Exhibits 8-10, and indicated in a status report that the medical file was then sufficiently complete for expert review. (ECF No. 22.) Ultimately, Petitioners filed the expert report, curriculum vitae, and list of prior trials and depositions, of Dr. Donald Marks on April 11, 2014. (ECF No. 28.)[6]

On August 15, 2014, Respondent filed two expert reports. (ECF Nos. 36-37.) A report by Dr. Max Wiznitzer was filed as Exhibit A, with accompanying curriculum vitae filed as Exhibit B. (ECF No. 36.) Supporting literature was filed as Exhibits C through F. (*Id*.) In addition, a report by Dr. Edward Cetaruk was filed as Exhibit G, along with a curriculum vitae marked as Exhibit H. (ECF No. 37.)

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[5] The document itself is mis-captioned as having been filed on November 20, 2002. (*See* ECF No. 16, p. 1.) Both the date of service and the date of signature, however, clearly indicate that the document was created and filed on November 26, 2008. (*Id*., p. 2.)

[6] Unfortunately, petitioners initially improperly designated Dr. Marks' materials as Exhibits 1-4. (*See* ECF No. 28.) Petitioners were ordered to correct that mistake on May 2, 2014. (ECF No. 30.) Petitioners refiled these materials on May 5, 2014, improperly designating them as Exhibits 7-10. (ECF No. 31.) Petitioners were again ordered to refile Dr. Marks' materials (ECF No. 32) and did so on May 15, 2014, designating the materials as Exhibits 11-14. (ECF No. 33.) (I will refer to Dr. Marks' report as Ex. 11, and his CV as Ex. 12.)

On August 18, 2014, I issued an order requesting that Petitioners indicate how they wished to proceed. (ECF No. 38.) On December 1, 2014, Petitioners filed a status report asking that I make a ruling based on the record. (ECF No. 41.)

The case is therefore ripe for decision without hearing and on the written record.

IV

FACTUAL HISTORY

J.R.B. was born on August 7, 1998. (Ex. 5, p. 2.) He was delivered via cesarean section due to breech presentation after 38 weeks of gestation. (*Id*., pp. 4-6.) No significant neonatal complications were recorded (*id*., p. 5) and he was discharged on August 10, 1998, weighing approximately 8.5 pounds (*id*., pp. 3-4). Upon discharge he was reported as having an undescended testicle[7] and a small mandible, but these conditions were considered stable. (*Id*., p. 4.) Newborn genetic screening was normal. (Ex. 1, p. 15.)

Early "well child" visits initially indicated normal development in the first months of life, with some reports of constipation. (Ex. 1, pp. 8-14.) In December of 1998, it was noted in J.R.B.'s four-month well-visit that he was not yet rolling. (Ex. 6, p. 277.) By February of 1999, J.R.B. was rolling, but he was not yet sitting, turning to voice, transferring objects, or bearing weight on his legs. (*Id*., p. 275.) In May of 1999, his nine-month well visit indicated that he did not yet stand or cruise, but sat alone and pulled to stand. (*Id.*, p. 272.) Well child visits at 18 months and 2 years did not record any developmental concerns.[8] (*Id*., pp. 255, 260.)

During this time period, J.R.B. received routine childhood vaccinations as follows. On August 19, 1998, J.R.B. received his first hepatitis B ("Hep B") vaccination. (Ex. 6, p. 1.) A few months later, on October 6, 1998, he received the first of his diphtheria, tenanus, and acellular pertussis ("DTaP"), haemophilus influenza type B ("Hib"), and live polio ("OPV") vaccinations, as well as his second Hep B vaccination. (*Id*.) On December 7, 1998, he received his second vaccinations of DTaP, Hib, and OPV. (*Id*.) His third doses of DTaP and Hib were administered on February 9, 1999. (*Id*.) Later that same year, he received a third dose of Hep B vaccine on May 10; a measles, mumps, and rubella ("MMR") vaccination on August 19; his fourth Hib vaccination on November 15; and a hepatitis A ("Hep A") vaccination on December 7. (*Id*.) Finally on February 10, 2000, he received his fourth DTaP and his third OPV. (*Id*.) Additionally he later received a varicella vaccination in February of 2007. (*Id*.)

Mrs. Bushnell began to have concerns about J.R.B.'s development when he was about 18 months old. (Ex. 9, p. 13.) Shortly after he turned two, J.R.B.'s pediatrician started early intervention for an expressive language delay. (Ex. 9, p. 13; Ex. 10, p. 6.) Initially he was followed by an educator every other week and attended a play group once a week. (Ex. 9, p. 13.) After about five months, Mrs. Bushnell became concerned about J.R.B.'s slow progress. (Ex. 9,

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[7] J.R.B. would later have corrective surgery for this condition at 4 years of age. (Ex. 6, pp. 278-79.)

[8] In addition to well-child visits, J.R.B.'s medical records also reflect a number of sick child visits during his first two years, including treatment for multiple upper respiratory infections and ear infections, as well as pharyngitis/strep throat and unidentified viral illnesses. (*See, e.g*., Ex. 6, pp. 256-76.)

p. 13; Ex. 10, p. 6.) He began receiving speech therapy twice a week and ABA therapy for 28 hours a week. (Ex. 9, p. 13.)

At about that time, J.R.B. was evaluated at the Franciscan Children's Hospital on May 14, 2001. (Ex. 10, pp. 6-7.) The assessment for that evaluation was "developmental delays of unknown etiology, expressive language delay, and mild hypotonia with mild motor skills delay." (*Id.*, p. 7.) Follow up was recommended to test for chromosomal abnormalities and "fragile X syndrome," and to assess J.R.B.'s hearing. (Ex. 10, p. 7.) J.R.B. was negative for fragile X, and no chromosomal abnormalities were found. (Ex. 10, pp. 9-13.) His hearing was later confirmed as adequate for communication and development. (*Id.*) Subsequently, on May 31, 2001, J.R.B.'s pediatric records referenced a potential "PDD"--*i.e.*, "pervasive developmental delay." (Ex. 6, p. 247.)

On June 26, 2001, J.R.B. was evaluated to determine whether he met the diagnostic criteria for an ASD. (Ex. 9, p. 11.) The evaluation team concluded that J.R.B. "does have a significant expressive language delay and a much more mild receptive language delay. However, he has no other of the DSM IV symptoms that would meet the criteria for autistic disorder or PDD, NOS." (*Id.*, p. 14.) Based on the evaluation, they continued, "the best diagnosis for [J.R.B.] at this time is a developmental language disorder with some mild impairment in social interaction skills that may be secondary to his language delay as well as some attentional difficulties that interfere with his ability to learn." (*Id.*) The team further stressed that J.R.B. benefitted from his ongoing special education services and speech therapies and that they should be continued. (*Id.*)

A team at Boston Children's Hospital Developmental Medicine Center, however, disagreed with the conclusion reached during the June 26, 2001 evaluation. (*See*, Ex. 2, pp. 82-90.) Following an evaluation on August 1, 2001, the team concluded that:

> [J.R.B.] was very self-directed and had limited communication. [J.R.B.] also has been noted to have difficulty with language acquisition, from both receptive and expressive standpoints. During our assessment, he uttered simple one word statements inconsistently and used some sign language to communicate simple needs such as hunger. He had significant difficulty in behavioral interactions with other caregivers and examiners with reduced reciprocal gaze and responsive interactions. [J.R.B.] seems to enjoy the physical aspects of toys more than their representational use in play or life circumstances. Because of all of these attributes, we feel that it is appropriate to diagnosis [sic] [J.R.B.] with autism.

(*Id.*, pp. 87-88.)

The Boston Children's Hospital team noted that this diagnosis was a departure from J.R.B.'s prior evaluations, but stressed that they believed it was the appropriate diagnosis "considering his degree of difficulty in language, behavior, and social interactions." (*Id.*, p. 88.) A follow-up developmental evaluation at Boston Children's Hospital on April 5, 2002, indicated that although he was still delayed, J.R.B. was making developmental progress and showed some skills improvement. (Ex. 2, pp. 71-76.) It was also noted that "he has shown no developmental

regression over the past six months."[9] (*Id*., p. 72.) His condition was noted as being consistent with PDD-NOS ("pervasive developmental disorder, not otherwise specified"), a form of ASD. (*Id*., p. 74.)

Thereafter, J.R.B. continued undergoing numerous tests and evaluations over the succeeding years, with diagnostic impressions varying as between "ASD," "PDD-NOS," and "global development delay." Throughout this time, J.R.B. also underwent genetic and nutritional evaluations. Eventually, J.R.B. was diagnosed as having complex I, II, IV, and ETC enzyme deficiency as well as muscle coenzyme Q10 deficiency. (Ex. 8, p. 14.) He began vitamin cocktail treatments for his mitochondrial disorder in 2009. (Ex. 7, p. 5.) After that point, his mother reported that his behavior disturbances decreased and his flapping disappeared. (*Id*.) Subsequent follow-up, however, indicated no significant improvement or deterioration in his function. (Ex. 7, p. 3.) And while he continued to make progress, his ASD symptoms persisted although his neurological exams remained stable. (Ex. 8, pp. 13-14.)

J.R.B.'s medical records note that as of April 19, 2012, he was a 13-year old boy with autism and mitochondrial disorder (complex I, II, IV ETC enzyme deficiency, as well as muscle coenzyme Q10 deficiency), and also suggest an additional later diagnosis of PANDAS.[10] (Ex. 8, pp. 13-14.)

V

ISSUE TO BE DECIDED

Petitioners contend that J.R.B.'s autism was caused by one or more of a series of aluminum-containing and/or mercury-containing vaccines administered between October 6, 1998, and February 1, 2000,[11] which they claim aggravated his pre-existing mitochondrial disorder. After carefully considering all of the evidence, I conclude that Petitioners have failed to demonstrate that it is "more probable than not" that any vaccinations contributed to causing or aggravating their son's condition, and that they have therefore *failed* to meet their burden. [12]

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[9] Years later, during a developmental evaluation on February 4, 2005, the Boston Children's Hospital staff again noted that a review of J.R.B.'s condition revealed that "he has had no regression or loss of skills." (Ex. 2, p. 33.)

[10] "PANDAS" is an abbreviation for pediatric autoimmune neuropsychiatric disorders associated with streptococcal infections. (Davis, Neil M., *Medical Abbreviations: 32,000 Conveniences at the Expense of Communication and Safety* (15th Ed.) (2011), p. 245.)

[11] The vaccinations placed at issue in this case include DTP/DaPT, Hib, OPV, MMR, Hep A, and Hep B. (*See* footnote 3, *supra*.) I note that the petition and amended petition characterize these vaccines only as mercury-containing; Petitioners' expert, however, additionally contends that they may contain aluminum as well.

[12] Petitioners have the burden of demonstrating the facts necessary for entitlement to an award by a "preponderance of the evidence." § 300aa-13(a)(1)(A). Under that standard, the existence of a fact must be shown to be "more probable than its nonexistence." *In re Winship*, 397 U.S. 358, 371 (1970) (Harlan, J., concurring).

Petitioners' theory of the case, though not very well explained by their expert, is apparently that vaccinations containing either mercury or aluminum, which are in themselves neurotoxins, act as stressors which can aggravate a mitochondrial disorder leading to neurological injury, and that individuals suffering from mitochondrial disorders are susceptible to ASDs in particular. In J.R.B.'s case, they argue the stress of his vaccines aggravated his underlying mitochondrial disorder and resulted in a regressive encephalopathy manifesting as autism.

Respondent, however, disputes both the scientific and factual basis for Petitioners' theory. Respondent argues that neither mercury nor aluminum, in the minuscule amounts contained in vaccines, has been shown to have the effects that Petitioners allege. Respondent also argues that there is no evidence to suggest that patients with mitochondrial disorders are vulnerable to these elements, or that vaccines cause autism among mitochondrial disorder patients. And, in any event, Respondent further argues that J.R.B.'s own clinical history is inconsistent with Petitioners' theory.

VI

SUMMARY OF EXPERT WITNESSES' QUALIFICATIONS AND OPINIONS

In this case, Petitioners rely on the expert report of one medical expert while respondent relies on the expert reports of two medical experts. At this point, I will briefly summarize both the qualifications and the opinions of those expert witnesses.

A. Petitioners' expert

1. Dr. Donald Marks

Petitioners rely primarily on the expert report of Donald H. Marks, M.D., PhD. Dr. Marks completed his undergraduate education in 1972 at the California State University, San Bernardino. (Ex. 12, p. 2.) He earned a Ph.D. in Microbiology from the University of California, Los Angeles, in 1977, and an M.D. from the same school in 1980. (*Id*., p. 3.) He completed a residency in internal medicine at the USAF Medical Center at the Keesler Air Force Base. (*Id*.) He is licensed by four states as well as by the National Board of Medical Examiners. He is also a Diplomat of the American Board of Internal Medicine. (*Id*., p. 4.) From 1980 to the present, Dr. Marks' clinical practice has focused on general internal medicine. (*Id.*, p. 1.) At present, he is a hospitalist at Apogee Physicians and Brookwood Medical Center in Birmingham, Alabama, as well as a clinical assistant professor at the University of Alabama at Birmingham Department of Medicine, in the Division of General Internal Medicine. (*Id*., pp. 1-2.)

In addition, Dr. Marks has many years of experience in clinical research and in the pharmaceutical industry. (Ex. 12, pp. 1-2.) He has published over 30 peer-reviewed articles, holds a number of patents concerning vaccines, and has testified extensively in a variety of trials and depositions. (Ex. 12, pp. 4-7; Ex. 13; Ex. 14.) He is a member of the editorial boards for *The International Journal of Risk & Safety in Medicine*, *The Internet Journal of Pharmacology*, and *Ethical Human Psychology and Psychiatry*. (Ex. 12, p. 8.)

2. Summary of Dr. Marks' opinion

Dr. Marks' report in this case stated that J.R.B. "may" have received vaccinations containing mercury, aluminum "and other toxic substances." (Ex. 11, p. 4.) He opined that both mercury and aluminum are "known to cause neurotoxic effects," and that J.R.B.'s documented mitochondrial disorder,[13] which he indicates is "known to cause ASD," left him "predisposed" to such alleged toxicity from vaccines. (*Id*.) He argued that J.R.B.'s vaccinations "significantly aggravated an underlying mitochondrial disorder which predisposed him to deficits in cellular energy metabolism and manifested as ASD." (*Id*.) He also asserted that what J.R.B. experienced was a "regressive encephalopathy." (*Id*., pp. 2-3.)

Dr. Marks argues that there is no expected temporal association for such an injury, stating that "there are vaccines which can cause either a more rapid or less rapid neurotoxicity, so either response is seen and documented in the medical literature. Time to injury itself does not include or exclude vaccine injury." (Ex. 11, p. 3.) Rather, Dr. Marks indicated J.R.B.'s condition could be linked to his vaccinations through a "documented stepwise regression after each vaccine administration" which he argued "demonstrated a consistent challenge-rechallenge response." (*Id*.)

B. Respondent's experts

1. Dr. Max Wiznitzer

Respondent relies in part on the expert report of Dr. Max Wiznitzer. Dr. Wiznitzer attended the Northwestern University Honors Program and specialized in Medical Education, earning a Bachelor of Science degree in Medicine in 1975 before entering medical school. (Ex. B, p.1.) He attended Northwestern University Medical School and graduated in 1977 with a degree in medicine. (*Id*.) During his postgraduate training, Dr. Wiznitzer was a resident in pediatrics at the Children's Hospital Center in Cincinnati, Ohio from 1977 to 1980. (*Id*.) He also was a fellow in developmental disorders at the Cincinnati Center for Developmental Disorders from 1980 to 1981. (*Id*.) He thereafter became a fellow in pediatric neurology at the Children's Hospital of Philadelphia from 1981 to 1984. (*Id*.) He received the NIH National Research Service Award fellowship in Higher Cortical Functions from 1984 to1986. (*Id*., p. 2.) From 1986 to the present, Dr. Wiznitzer has been an Assistant Professor of Pediatrics, Neurology, and International Health at Case Western Reserve University. (Ex. B, p. 2.)

Dr. Wiznitzer has additionally won the NIG National Research Service Award from the Albert Einstein College of Medicine in 1986, and was recognized as the Professional of the Year from the Autism Society of Ohio in 1991. (Ex. B, p. 3.) He was certified by the American Board of Pediatrics in 1982, the American Board of Psychiatry and Neurology with special qualification in Child Neurology in 1986, and the National Board of Medical Examiners in 1978. (Ex. B, p. 5.) He has been licensed to practice in three states. (Ex. B, p. 5.) Dr. Wiznitzer served

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[13] I note that the experts in this case appear to use the terms mitochondrial *disease* and mitochondrial *disorder* interchangeably. Dr. Marks in particular uses both terms within his expert report, while Dr. Wiznitzer seems to prefer to use the term disorder and Dr. Cetaruk uses the term disease. For the sake of consistency, this opinion will use the term disorder except where quoted source material uses the term disease; however, no distinction is intended by such word choice.

on the Editorial Board of *Pediatric Neurology*, *Journal of Child Neurology*, and *Lancet Neurology*. (*Id*., p. 6.) He has helped author 58 original articles, 11 book chapters, and 55 abstracts, which are listed on his CV. (*Id*., pp. 13-23.)

2. Summary of Dr. Wiznitzer's opinion

Dr. Wiznitzer disagreed with Dr. Marks' assertion that J.R.B. experienced a neurologic regression following vaccination. Rather, upon his detailed review of the medical records, Dr. Wiznitzer concluded that the onset of J.R.B.'s ASD "fits one of the identified development trajectories – acquisition of some words * * * followed by apparent expressive/stagnation/slowing of expressive language development with gradual appearance of impaired socialization." (Ex. A, p. 9.) He further argued that in fact there is "no history in the contemporaneous medical records of an autistic regression." (*Id*.) Dr. Wiznitzer also noted that "there is no documentation of any adverse event following immunization in his contemporaneous medical records," and that there were "multiple febrile illnesses (8 in the first 2 years of life) that were not associated with or followed by neurologic regression." (Ex. A, p. 10.) Dr. Wiznitzer argued that this, among other factors, casts doubt on Dr. Marks' suggestion that J.R.B.'s autism was caused by mitochondrial stress. (*Id*.) He also stressed that Dr. Marks' theory lacks a plausible biological basis, in that he has not provided sufficient data regarding the toxicity of either mercury or aluminum. (*Id*.) He also argued there is insufficient evidence that J.R.B. experienced an "acute" encephalopathy. (*Id*.)

3. Dr. Edward Cetaruk

In addition to Dr. Wiznitzer's report, Respondent is also relying on a report prepared by Dr. Edward Cetaruk. Dr. Cetaruk is a 1986 graduate of the University of Massachusetts at Amherst. (Ex. H, p. 2.) He completed his M.D. at the New York University School of Medicine in 1991 and a residency in emergency medicine at the University of Massachusetts Medical Center in Worcester, Massachusetts in 1994. (*Id*.) From 1994 to 1996 he completed fellowships in emergency medicine and medical toxicology. (*Id.*, p. 1.) Currently, Dr. Cetaruk is an attending faculty member at the Rocky Mountain Poison and Drug Center as well as an assistant clinical professor in the Section of Clinical Pharmacology and Toxicology at the University of Colorado Health Sciences Center Department of Medicine. (*Id*.) He also maintains a private medical practice focusing on toxicology through the medical group Toxicology Associates. (Ex. G, p. 2; Ex. H, p. 3.)

Dr. Cetaruk is a member of the American Academy of Clinical Toxicology, the American College of Medical Toxicology, and the American College of Emergency Physicians. (Ex. H, p. 4.) He has been licensed to practice medicine in three states and is a Diplomate of the American Board of Emergency Medicine with special qualification in medical toxicology, as well as the American Board of Emergency Medicine and the National Board of Medical Examiners. (Ex. H, pp. 1-2.) He lists 27 publications on his curriculum vitae as well as numerous invited lectures. (Ex. H, pp. 5-10.)

4. Summary of Dr. Cetaruk's opinion

Dr. Cetaruk contended that there is no causal connection between J.R.B.'s vaccinations and his development of ASD. He argued that vaccinations do not contain sufficient doses of

either mercury or aluminum to be poisonous, and that even if a poisoning occurred by those elements, such poisoning would not manifest as autism. (Ex. G, p. 8.) He further noted that there is no evidence to suggest that mercury or aluminum in vaccines "sets off" or "triggers" regressive encephalopathy among mitochondrial patients or that such patients are vulnerable to those elements. (*Id*.) Dr. Cetaruk also disputed Dr. Marks' claim that the immune response from aluminum adjuvants contained in vaccines could have exacerbated J.R.B.'s mitochondrial disorder. (*Id*.) He stressed the lack of reliable scientific data to support Dr. Marks' theory. (*Id*.)

VII

SUMMARY OF MY DECISION

I find that Dr. Marks' causation theory was *entirely* unsupported. Even without considering Respondent's competing expert evidence, Dr. Marks very brief report is utterly unpersuasive, in that it fails to articulate sufficient support for his opinion in either the factual record of this case or in the relevant medical literature. Indeed, Dr. Marks' report has no evidentiary support whatsoever. Moreover, Dr. Marks' report is far outweighed by the reports of Respondent's experts. The reports prepared by Drs. Wiznitzer and Cetaruk – both of whom have superior credentials in the relevant fields – were far more persuasive in that they were more detailed, more coherent, and better supported by the facts of J.R.B's case and the relevant medical literature.

VIII

DR. MARKS' EXPERT REPORT IS PATENTLY INSUFFICIENT TO SUPPORT PETITIONERS' CLAIM

Dr. Marks' report was spare to an untenable degree. His recitation of J.R.B.'s clinical history is notable in that it is almost completely absent, and Dr. Marks did almost nothing to link his causation opinion to the facts of J.R.B.'s case. His discussions of both autism and mitochondrial function were vague and insufficiently explained. At times his report seemed confused regarding which mechanism of injury was being proposed, and he provided no citations to support his most critical points. In short, even before considering Respondent's competing submissions, Dr. Marks' report--which is undoubtedly the linchpin of Petitioners' claim on this record--suffers numerous flaws which leave it inherently inadequate to establish vaccine causation in this case.

A. Dr. Marks' theory finds no support in J.R.B.'s medical records.

Most glaringly, Dr. Marks' entire opinion is predicated on an incorrect reading of J.R.B.'s medical record. The only evidence that Dr. Marks cited which would indicate his theory might be at work in J.R.B.'s case was the claim that "the injuries from vaccines received by JB caused a documented stepwise regression after each vaccine administration, and this demonstrated consistent challenge – re-challenge responses." (Ex. 11, p. 3.) Absent such a "challenge-re-challenge" response, Dr. Marks made no attempt to link his theory to J.R.B.'s own clinical history. In fact, Dr. Marks explicitly rejected any other measure of a temporal association between J.R.B.'s vaccinations and his autism, stating that "time to injury itself does not include

or exclude vaccine injury." (Ex. 11, p. 3.) J.R.B.'s medical records, however, do not support a "challenge-rechallenge" response.[14]

As detailed above, the vaccinations at issue in this case were administered between October 6, 1998, and February 10, 2000. (*See* footnote 3, *supra; see also* Ex. 6, p. 1.) Thus, J.R.B. having been born on August 7, 1998, the last of the relevant vaccinations was administered around the time J.R.B. reached 18 months of age. The histories contained in the medical records, however, place the onset of J.R.B.'s developmental delays sometime between 18 months and two years of age--*i.e.,* no earlier than after the *conclusion* of his series of vaccinations. (*See, e.g.*, Ex. 2, p. 82; Ex. 9, p. 13.) There is, therefore, no basis to assert that a challenge-rechallenge response was present. There is simply no evidence that there was a "stepwise regression after each vaccine administration," as Dr. Marks specifically claimed. The medical records do not support the contention that J.R.B. experienced any developmental setbacks *during the course of* his series of vaccinations, let alone discernable regressions after each vaccination. And even assuming *arguendo* that the onset of J.R.B.'s developmental concerns at about 18 months constituted a challenge event, there is no evidence of any subsequent re-challenge. As Dr. Witzniter indicated in his report, once onset occurred J.R.B. followed a trajectory of delays (and even some improvement) without subsequent regression. (Ex. A, p. 9.) Indeed, J.R.B.'s medical records explicitly note on multiple occasions the absence of regression.[15] (Ex. 2, pp. 33, 72.)

Thus, because Dr. Marks' opinion is based on a false assumption regarding the onset of J.R.B.'s condition, and the incorrect assumption of a "stepwise regression" after each vaccine administration, it should not be credited. *See, e.g., Rickett v. HHS*, 468 Fed. Appx. 952, 958 (Fed. Cir. 2011)(holding that "it was not error for the Special Master to assign less weight to Dr. Bellanti's conclusion regarding challenge-rechallenge to the extent it hinged upon Mr. Rickett's testimony that was inconsistent with the medical records."); *see also Dobrydnev v. HHS*, 566 Fed. Appx. 976, 982-83 (Fed. Cir. 2014) (holding that the special master was correct in noting that "when an expert assumes facts that are not supported by a preponderance of the evidence, a finder of fact may properly reject the expert's opinion") (citing *Brooke Group Ltd. v. Brown & Williamson Tobacco Corp.*, 509 U.S. 209, 242 (1993)).

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[14] The "challenge-rechallenge" concept has been addressed in numerous cases within the Vaccine Program. Most notably, the Federal Circuit succinctly summarized the theory by explaining that "a rechallenge event occurs when a patient who had an adverse reaction to a vaccine suffers worsened symptoms after an additional injection of the vaccine." *Cappizano v. HHS*, 440 F.3d 1317, 1322 (Fed. Cir. 2006).) To successfully establish a challenge-rechallenge theory, a petitioner must show a temporal relationship between the occurrence of petitioner's symptoms and multiple vaccine administrations. *See, e.g., Doe v. HHS*, 95 Fed. Cl. 598, 609 (2010)(affirming the decision of the special master and noting that "the special master found that petitioner had not established causation by a preponderance of the evidence because neither of his expert's proposed 'challenge events' had the necessary temporal connection to the first or second dose of the vaccine.")

[15] A later parental history does indicate that Mrs. Bushnell reported a regression in speech, but this record also indicates that she perceived J.R.B. to be "normal" as late as two and a half years of age. (Ex. 6, p. 45.) This account is not consistent with the earlier records which clearly show that J.R.B. began early intervention at about two years of age as a result of Mrs. Bushnell's concerns at that time. (*See, e.g.*, Ex. 9, p. 13; Ex. 10, p. 6.)

B. Dr. Marks' report failed to identify which, if any, of J.R.B.'s vaccinations were allegedly causative.

In addition to the above, Dr. Marks' report is further undercut by his apparent inability or unwillingness to address the specific details of J.R.B.'s vaccination history. Not only did Dr. Marks fail to specifically discuss J.R.B.'s medical records, Dr. Marks did not even actually indicate which of J.R.B.'s vaccinations he believes to be potentially causative. (Ex. 11, p. 1.) That is, despite opining that J.R.B.'s condition was the result of neurotoxic effects of mercury and aluminum, at no point did Dr. Marks attempt to establish which of J.R.B.'s vaccinations contained those elements. Rather he stated that J.R.B. "is a child who received multiple vaccinations which *may have* contained mercury, aluminum, and other toxic substances." (Ex. 11, p. 4 (emphasis added).) His opinion stops short, however, of committing to any opinion that J.R.B. *actually received* a vaccine containing what he contends is a neurotoxic substance. Instead, Dr. Marks begs the question by speculating that "*any* of the vaccines JB received *may have been* a trigger for exacerbating his regression." (Ex. 11, p. 2 (emphasis added).) Thus, his opinion is inherently speculative.

C. It is not clear what mechanism of injury Dr. Marks is relying upon.

Dr. Marks' report was also unclear regarding the mechanism of injury he believes to be operative in the development of J.R.B.'s condition. It appears, from Dr. Marks' repeated references to "neurotoxicity," that he believes the ultimate source of harm to J.R.B. was the mercury and/or aluminum contained in his vaccinations. (Ex 11, *passim*.) Confusingly, however, his report was very unclear in stating *how* those elements would have acted to create such harm.

Dr. Marks postulated that the inflammatory response created by aluminum adjuvants could exacerbate an underlying mitochondrial disorder and in turn result in local hypoxia and lactic acid build-up. (Ex. 11, p. 2.) He also repeatedly lumped aluminum and mercury together as elements in vaccines that "produce toxicity to the brain," apparently positing a direct response. (*See, e.g.,* Ex. 11, pp. 2, 3, 4). In addition, he cited "neuroimmune" disorders as potentially involved, and indicated that the vaccines at issue acted as "immunological stressors." (Ex. 11, p. 2.) None of these potential mechanisms, however, was explained. Nor was there any indication of whether, in Dr. Marks' view, they acted in combination, or whether they are mutually exclusive alternative theories.[16]

Of course, petitioners are not obligated to prove the *mechanism* of injury as part of their burden of proof. (*See, e.g., Knudsen v. HHS*, 35 F.3d 543, 549 (Fed. Cir. 1994.).) Nonetheless, Dr. Marks' seeming inability to *coherently* articulate a theory of causation undermines

[16] Moreover, in his final conclusion, Dr. Marks muddied the waters further by claiming that J.R.B.'s mitochondrial disorder itself is "known to cause ASD." (Ex. 11, p. 4.) Contrary to the above, this suggests that perhaps Dr. Marks does not necessarily believe that J.R.B.'s *vaccinations* were a "but for" cause of his condition, but rather implies that the mitochondrial disorder *itself* could have resulted in ASD *without* any vaccine involvement at all.

Petitioners' case as a whole. Dr. Marks' report merely postulates a number of possibilities without adequately explaining or substantiating any of them.

D. Dr. Marks' causation theory lacks scientific support.

In any event, I have reviewed the references that Dr. Marks cited in his report, and, regardless of the specific mechanism at work, none of these sources offers significant support for his assertions. Most of Dr. Marks' supporting citations point to general resources relating to mitochondrial disorders and dysfunction, autism, and general principles of medical causation. (*See* Ex. 11, p. 5.) These sources do not address in any meaningful way the issues actually controverted in this case, let alone support Dr. Marks' specific contentions. Indeed, as Dr. Cetaruk points out, several of Dr. Marks' *own citations* actually refute his assertions. (Ex. G, pp. 6-7.)

For example, Dr. Marks cites a vaccine safety webpage regarding thimerosal of the Centers for Disease Control and Prevention ("CDC"). (Ex. 11, p. 5, Ref. 2.) On that webpage, the CDC states that "there is no convincing evidence of harm caused by the low doses of thimerosal in vaccines, except for minor reactions like redness and swelling at the injection site." (*See* http://www.cdc.gov/vaccinesafety/concerns/thimerosal/, last accessed January 26, 2015.) Similarly, Dr. Marks cites a "Questions and Answers" guide to thimerosal in vaccines posted on the Food and Drug Administration ("FDA") website. (Ex. 11, p. 5, Ref. 3.) Like the CDC, the FDA similarly notes that "[u]nder the FDA Modernization Act (FDAMA) of 1997, FDA carried out a comprehensive review of the use of thimerosal in childhood vaccines. Conducted in 1999, this review found no evidence of harm from the use of thimerosal as a vaccine preservative, other than local hypersensitivity reactions." (*See* http://www.fda.gov/biologicsbloodvaccines/vaccines/questionsaboutvaccines/ucm070430.htm, last accessed January 26, 2015.)

Dr. Marks himself effectively conceded this point, noting that "recent expert reviews have concluded that mercury toxicity from vaccines does not lead to autism." (Ex. 11, p. 2.) Although he attempted to discount those studies by asserting that "these reviews were not focused on populations exhibiting mitochondrial defects" (*id*.), he has failed to come forward with any studies that have found, or would otherwise purport to explain, any link between vaccines and autism among that population.

Similarly, although he additionally claimed that "[s]ome expert reviews have also concluded that aluminum adjuvants have the potential to cause neuroimmune disorders," he did not specify what expert reviews he was relying upon in making that statement, nor do any of the citations in his report support that claim. (Ex. 11, pp. 2, 5.) For his part, Dr. Cetaruk stated that in fact "[t]here are no cases published in the peer-reviewed medical literature that report aluminum toxicity, including neurotoxicity, due [to] the doses of aluminum found in vaccines." (Ex. G, p. 6.)

In addition, Dr. Marks' report is noteworthy for arguing that there is an association between mitochondrial disorders and ASD. He stated that "mitochondrial disease may affect any part of the body, including the muscles and various organs, and presents along a wide spectrum. * * *. A child with mitochondrial disease may have autism, may only have some symptoms of autism, or may have no symptoms of autism." (Ex. 11, p. 2.) More specifically, Dr. Marks

asserted that mitochondrial disorders are "known to cause ASD." (Ex. 11, p. 4.) Yet, the CDC webpage he cites among his references disagrees. It states that "more research is needed to find out how common it is for people to have autism and a mitochondrial disorder. Right now, it seems rare. In general, more research about mitochondrial disease and autism is needed." (Ex. 11, p. 5, Ref. 5; *See* http://www.cdc.gov/ncbddd/autism/mitochondrial-faq.html, last accessed 1/29/15.) Moreover, the Rossignol and Frye article cited by Dr. Marks, while finding some evidence of an association between ASDs and mitochondrial dysfunction, likewise indicates that more studies are needed to understand the relationship. (Ex. 11, p. 5, Ref. 5; *Mol Psychiatry*, Mar 2012; 17(3): 290-314.)

These citations indicate that Dr. Marks, at best, grossly overstated the scientific support for his claims. Thus, he has not even purported to minimally support his foundational assertion that childhood vaccines can have neurotoxic effects at all, let alone that any such effect could combine with a mitochondrial disorder to manifest as autism. All of his citations are either silent regarding his specific contentions or are actually contradictory to the claims made in his report. His report is therefore patently insufficient. *See, e.g., Caves v. HHS*, 100 Fed. Cl. 119, 134 (2011), *aff'd*, 463 F. App'x 932 (Fed. Cir. 2012)(quoting *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997) for the proposition that "*Daubert* does not require a trial court 'to admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert.'").[17]

E. The OAP test cases have already addressed the question of vaccine toxicity to the brain.

Dr. Marks' failure to convincingly address the question of mercury and/or aluminum toxicity to the brain is particularly glaring in light of the prior OAP test cases which addressed related questions. As noted above, the second set of OAP test cases considered the theory that the thimerosal component of vaccines could cause autism. *See Dwyer v. HHS*, No. 03-1202V, 2010 WL 892250 (Fed. Cl. Spec. Mstr. Mar. 12, 2010); *King v. HHS*, No. 03-584V, 2010 WL 892296 (Fed. Cl. Spec. Mstr. Mar. 12, 2010); *Mead v. HHS*, No. 03-215V, 2010 WL 892248 (Fed. Cl. Spec. Mstr. March 12, 2010). In addressing this question, those cases *extensively* reviewed the science regarding the possible neurotoxicity of thimerosal, and uniformly concluded that no link between thimerosal-containing vaccines and autism had been established.

Although Dr. Marks' theory seems to differ somewhat from the OAP test cases, in contending that J.R.B. was susceptible to these alleged neurotoxic effects by virtue of his mitochondrial disorder, he has not substantiated that assertion. (*See* Section VIII(D) above.) Moreover, the fact remains that his theory is still predicated on the alleged neurotoxicity of thimerosal and aluminum as contained in vaccines. The OAP test cases decisively decided

[17] To be clear, I am not requiring the Petitioners in this case, or the petitioners in any case, to necessarily produce medical literature directly on point. In any particular case, a petitioner could prevail by providing a persuasive medical *opinion* in lieu of medical literature, especially where the scientific field is "bereft of complete and direct proof of how vaccines affect the human body." (*see Althen*, 418 F.3d at 1280). However, in this case, Dr. Marks' failure to identify any supporting medical literature (which he claims does exist at least as regards aluminum toxicity) in the face of his acknowledgment that contrary literature exists, as well as his citation to sources which actually contradict his opinion, weighs heavily against accepting his opinion in this case. This is not a case where the field is bereft of proof, but rather a case where the Petitioners' expert has utterly failed to demonstrate that the existing literature supports his view, or even to address the subject matter in any detail at all.

against, *inter alia*, any neurotoxic effect of the thimersosal contained in vaccines and, as described in Section VIII(D) above, Dr. Marks has offered no significant evidence to the contrary. The result of the OAP test cases, of course, are *not* binding in any other case. Nonetheless, to the extent that the issues overlap, it is quite noteworthy that the *huge* amount of evidence in those test cases proved wholly *contradictory* to the claim that the thimerosal component of vaccines could contribute to autism--and that huge volume of evidence contrasts strikingly to Dr. Marks' extremely sparse, unsupported opinion.

IX

RESPONDENT'S EXPERTS WERE FAR MORE PERSUASIVE

For the reasons described above, I find that Petitioners' expert opinion is inadequate to support Petitioners' claim, and can be readily dismissed. Further, I additionally note that Respondent's experts were *far* more persuasive. Drs. Wiznitzer and Cetaruk, in addition to having vastly superior credentials, offered much greater detail within their reports, and more coherently and effectively communicated the basis for their opinions in this case.

A. Respondent's experts are far more qualified than Dr. Marks.

The qualifications of the three experts in this case are more fully addressed in Section VI above. At this point, however, I will briefly reiterate that Drs. Wiznitzer and Cetaruk have expertise that is far more closely matched to the issues in this case than the expertise of Dr. Marks.

Dr. Marks' medical career has been predominantly one devoted to general internal medicine. (*See* Ex. 11.) Indeed, his clinical practice has been entirely devoted to general and hospital medicine. (Ex. 11, p. 1.) His curriculum vitae offers no indication of any special competency related to either the diagnosis or treatment of ASDs, such as J.R.B. suffers; nor does Dr. Marks claim any such expertise in his report. (*See* Exs. 11, 12.)

Dr. Wiznitzer, on the other hand, is a pediatrician and neurologist who has devoted his career to the diagnosis and treatment of ASDs. His *curriculum vitae* demonstrates that he has worked for more than 30 years in the field of pediatric developmental disorders with a particular focus on autism. (*See* Ex. B.) For example, he spent nearly 20 years as director of the Rainbow Autism Center (Ex. B, p. 3) and has been a child neurology liaison to both the American Academy of Pediatrics Autism Subcommittee and the Autism Treatment Network (Ex. A, pp. 1-2).

Dr. Marks' professional biography is noteworthy in that he does hold a Ph.D. in Microbiology in addition to his M.D., and claims "over 20 years of experience in pharmaceutical and vaccine medicine," as well as "several patents concerning vaccines." (Ex. 11, p. 1.) However, neither his listed patents nor his graduate studies identify any focus on toxicology, as would be relevant regarding his claims of alleged mercury and aluminum neurotoxicity. (Ex. 12, pp. 2-4.) Indeed, his graduate studies focused on plant physiology and immunology. (Ex. 12, p. 3.) And while some of Dr. Marks' peer-reviewed publications relate to toxicology, many more relate to other subjects such as bacterial and viral infection. (Ex. 12, pp. 5-7.) Moreover, despite working in research and regulatory affairs within the pharmaceutical industry, Dr. Marks has no

certification in either pharmacology or toxicology, nor has he ever held any clinical practice position in either field. (Ex. 12, pp. 1-4.)

Dr. Cetaruk, in contrast, has an extensive career focused particularly on medical toxicology, which, pertinent to this case, he describes as a specialization in "the assessment, diagnosis and treatment of adverse effects of pharmaceuticals, non-therapeutic chemicals, natural toxins, envenomations, as well as other potential toxicants and toxicological conditions." (Ex. G, p. 2.) He is board-certified in emergency medicine with a special qualification in medical toxicology, and is an assistant clinical professor in Clinical Pharmacology and Toxicology at the University of Colorado. (Ex. H, p. 1.) He is a past chair of the American Academy of Clinical Toxicology Committee on Chemical Terrorism and a manuscript reviewer for the *Journal of Toxicology*. (Ex. H, p. 4.) His curriculum vitae lists numerous toxicological papers and presentations. (Ex. H, pp. 6-10.)

In sum, Respondent's experts are far more qualified to speak to the question of whether tiny amounts of aluminum and mercury contained in some vaccines can contribute to the development of autism. They have far superior qualifications in the relevant areas of pediatric developmental disorders, including autism in particular, and toxicology.

B. Respondent's experts have fully rebutted Dr. Marks' report.

It is also significant that in addition to being better qualified, Respondent's experts produced reports that are of a higher quality and far more convincingly address the issues in this case. Their reports fully rebut Dr. Marks' causation opinion in this case.

First, I note that Dr. Wiznitzer, following a lengthy and detailed summary of J.R.B.'s complete medical history, persuasively argues that Dr. Marks has not fully accounted for that history. Indeed, whereas Dr. Marks failed to fully discuss J.R.B.'s medical history – instead simply referring the reader back to the medical records – Drs. Wiznitzer and Cetaruk both included extensive reviews of J.R.B.'s relevant history in their reports. (*Compare* Ex. 11, p. 1 to Ex. A, pp. 2-8; Ex. G, p. 3.)

Dr. Wiznitzer, in particular, argues that J.R.B.'s history, contrary to Dr. Marks' assertion, is not consistent with a "regressive encephalopathy," but rather "fits one of the identified developmental trajectories [of ASD] – acquisition of some words * * * followed by apparent expressive/stagnation/slowing of expressive language development with appearance of impaired socialization." (Ex. A, p. 9.) He notes that J.R.B.'s contemporaneous medical records report no regression, and that, in fact, J.R.B.'s co-existing developmental problems showed gradual but variable improvement over time. (Ex. A, p. 9.) He also notes that despite being diagnosed with a mitochondrial disorder, "vitamin cocktail" treatment has not resulted in any significant improvement of his ASD features.[18] (Ex. A, p. 10.)

[18] Petitioners make a point of alleging in their amended petition that after beginning his "vitamin cocktail," J.R.B.'s "behavior disturbances had dramatically decreased and his flapping movements had disappeared." (Am. Pet, p. 3.) And indeed, this improvement is noted in the interval history for his follow-up exam of October 7, 2009, as having been reported by his mother (albeit in response to treatment with antibiotics and not attributed to the vitamin cocktail). (Ex. 7, p. 5.) However, at his

Dr. Witznitzer further notes that J.R.B.'s stable head circumference suggests a lack of any acute encephalopathy. (Ex. A, p. 10.) He also argues that although acute encephalopathy can be seen among mitochondrial disorder patients following acute infectious illness, J.R.B.'s ability to withstand prior febrile illnesses, along with the lack of any noted adverse events following his immunizations, are facts inconsistent with Dr. Marks' contention that J.R.B. experienced neurologic regression related to his mitochondrial disorder after each vaccine. (*Id*.)

Dr. Marks' report does not even identify, let alone address the significance of, any of these facts. Indeed, Dr. Marks' most detailed description of J.R.B.'s medical history is that "J.B. is a male child who developed neurologic adverse effects after repeated vaccinations. He was subsequently diagnosed with autism and with a mitochondrial disorder." (Ex. 11, p. 2.)

Dr. Cetaruk's toxicological analysis was likewise far more detailed and coherent than Dr. Marks' competing interpretation. Although Dr. Cetaruk acknowledged that both mercury and aluminum *can* be neurotoxic, he stresses that the question of toxicity is *dose-dependent*. (Ex. G, p. 7.) He pointed out that the amounts of aluminum and mercury contained in vaccines are "magnitudes less" than the doses which have been shown to be neurotoxic. (*Id*.)

Dr. Cetaruk also explained that Dr. Marks' suggestion that "mercury" in vaccines acts as a neurotoxin is insufficient. He argued that the thimerosal contained in vaccines is metabolized to *ethylmercury*, which is distinct from *methylmercury*, a different type of mercury known to cause neurological damage if the dosage is sufficient. (Ex. G, p. 4.) Dr. Cetaruk cited studies showing not only that methlymercury is not a suitable reference to assess the risk of *thimerosal*, but also that human infants immunized with thimerosal-containing vaccines showed mercury levels below even the safety guidelines for *methylmercury*.[19] (Ex. G, pp. 4-5.)

Dr. Cetaruk further pointed out that Dr. Marks failed to distinguish between the two major types of aluminum vaccine adjuvant, aluminum hydroxide adjuvant and aluminum phosphate adjuvant. (Ex. G, p. 6.) After explaining at length the current understanding of how aluminum adjuvants function in the body, Dr. Cetaruk noted that the two different types of adjuvant have different chemical compositions, and can have different effects on the body's immune response depending on the vaccine's formulation. (*Id*.) He also asserted that "there are no cases published in the peer-reviewed medical literature that report aluminum toxicity, including neurotoxicity, due [to] the doses of aluminum found in vaccines." (*Id*.)

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subsequent follow-up, on October 20, 2010, J.R.B.'s father indicated that "there has been no significant improvement or deterioration in his function." (Ex. 7, p. 3.) Thereafter, subsequent follow-ups indicate that J.R.B. was making progress, and that his neurological exam was "stable." (Ex. 8, p. 17.) Features of ASD, such as poor eye contact, and understanding but not participating in conversations, remain evident in the records. (Ex. 8, pp. 13-14.)

In any event, whether or not J.R.B.'s "vitamin cocktail" treatment has caused any improvement in his ASD symptoms, there is no evidence in the record that the effectiveness of such a treatment would constitute an indication that *vaccinations* had played any role in causing or aggravating the ASD.

[19] I stress again, as discussed in Section VIII(E), that these issues were extensively explored in the OAP test cases.

In sum, Dr. Cetaruk argued that Dr. Marks has not presented a reliable scientific basis to conclude that any causal relationship exists between the aluminum and/or mercury contained in vaccines and ASD, the condition which affects J.R.B. (Ex. G, pp. 7-8.) In that regard, Dr. Cetaruk's point is well taken.[20] Dr. Marks failed not only to acknowledge any of the distinctions Dr. Cetaruk raised, but indeed failed to even address the actual dosages at issue in J.R.B.'s case. Moreover, as described in Section VIII(D) above, Dr. Marks also failed to show adequate scientific support for his assertions regarding the toxicity of either aluminum or mercury.

Thus, on the whole, I find that Drs. Wiznitzer and Cetaruk fully rebutted Dr. Marks' report. They noted that Dr. Marks remained silent on crucial points and failed to substantiate many of his claims. Perhaps more importantly, they also established that Dr. Marks' report is actually *contrary* to both the medical literature and the record of this case on key points.

X

PETITIONERS HAVE FAILED THE *ALTHEN* TEST

As noted above, in its ruling in *Althen,* the U.S. Court of Appeals for the Federal Circuit discussed the "causation-in-fact" issue in Vaccine Act cases. The court stated as follows:

> Concisely stated, Althen's burden is to show by preponderant evidence that the vaccination brought about her injury by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between the vaccination and injury. If Althen satisfies this burden, she is "entitled to recover unless the [government] shows, also by a preponderance of the evidence, that the injury was in fact caused by factors unrelated to the vaccine."

Althen, 418 F.3d 1274, 1278 (Fed. Cir. 2005)(citations omitted). In the pages above, I have already set forth in detail my analysis in rejecting Petitioners' "causation-in-fact" theory in this case. In this part of my Decision, then, I will briefly explain how that analysis fits specifically within the three parts of the *Althen* test, enumerated in the first sentence of the *Althen* excerpt set forth above. The short answer is that I find that Petitioners' theory in this case clearly does not satisfy the *Althen* test.

A. Relationship between Althen Prongs 1 and 2

One interpretive issue with the *Althen* test concerns the relationship between the first two elements of that test. The first two prongs of the *Althen* test, as noted above, are that the petitioners must provide "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury." Initially, it is not absolutely clear how the two prongs differ from each other. That

[20] I note that to the extent that Dr. Cetaruk's report set out to "prove a negative" --*i.e.*, to dispute Dr. Marks' theory of a causal link--much of his report is necessarily focused on the shortcomings of Dr. Marks' report.

is, on their faces, each of the two prongs seems to require a demonstration of a "causal" connection between the "vaccination" and "the injury." However, a number of Program opinions have concluded that these first two elements reflect the analytical distinction that has been described as the "can cause" vs. "did cause" distinction. That is, in many Program opinions issued prior to *Althen* involving "causation-in-fact" issues, special masters or judges stated that a petitioner must demonstrate (1) that the *type* of vaccination in question *can* cause the *type* of injury in question, and also (2) that the *particular* vaccination received by the specific vaccine *did* cause the vaccinee's *own* injury. *See, e.g., Kuperus v. HHS*, 2003 WL 22912885, at *8 (Fed. Cl. Spec. Mstr. Oct. 23, 2003); *Helms v. HHS*, 2002 WL 31441212, at *18 n. 42 (Fed. Cl. Spec. Mstr. Aug. 8, 2002). Thus, a number of judges and special masters of this court have concluded that Prong 1 of *Althen* is the "can cause" requirement, and Prong 2 of *Althen* is the "did cause" requirement. *See, e.g., Doe 11 v. HHS*, 83 Fed. Cl. 157, 172-73 (2008); *Nussman v. HHS*, 83 Fed. Cl. 111, 117 (2008); *Banks v. HHS*, 2007 WL 2296047, at *24 (Fed. Cl. Spec. Mstr. July 20, 2007); *Zeller v. HHS*, 2008 WL 3845155, at *25 (Fed. Cl. Spec. Mstr. July 30, 2008). And, most importantly, the *Federal Circuit* confirmed that interpretation in *Pafford*, ruling explicitly that the "can it?/did it?" test, used by the special master in that case, was equivalent to the first two prongs of the *Althen* test. *Pafford v. HHS*, 451 F.3d at 1352, 1355-56 (Fed. Cir. 2006). Thus, interpreting the first two prongs of *Althen* as specified in *Pafford*, under Prong 1 of *Althen* a petitioner must demonstrate that the type of vaccination in question can cause the type of condition in question; and under Prong 2 of *Althen* that petitioner must then demonstrate that the particular vaccination did cause the particular condition of the vaccinee in question.

Moreover, there can be no doubt whatsoever that the *Althen* test ultimately requires that, as an overall matter, a petitioner must demonstrate that it is "more probable than not" that the particular vaccine was a substantial contributing factor in causing the particular injury in question. That is clear from the statute itself, which states that the elements of a petitioner's case must be established by a "preponderance of the evidence." § 300aa-13(a)(1)(A). And, whatever is the precise meaning of Prongs 1 and 2 of *Althen*, in this case the overall evidence falls far short of demonstrating that it is "more probable than not" that any of the vaccines that J.R.B. received contributed to the causation of J.R.B.'s tragic neurodevelopmental disorder.

A. Petitioners have failed to establish Prong 1 of Althen in this case.

As explained above, under Prong 1 of *Althen* a petitioner must provide a medical theory demonstrating that the *type* of vaccine in question can cause the *type* of condition in question. Petitioners' theory is that some or all of J.R.B.'s vaccinations may have contained either mercury or aluminum, that these elements are neurotoxins, and that their neurotoxic effects ultimately aggravated J.R.B.'s mitochondrial disorder, resulting in a regressive encephalopathy manifesting as autism. (Ex. 11, pp. 2-4.) However, for the reasons set forth in detail above, Petitioners have not established that *any* vaccines contain mercury or aluminum in sufficient doses to be neurotoxic, which is the fundamental basis of their theory. Nor have they established either that individuals with mitochondrial disorders are predisposed to this alleged vaccine toxicity.[21] Thus, Petitioners' claim fails under *Althen* Prong 1.

[21] I further note that to the extent that Dr. Marks' report seemed, in a rather confused manner, to reference other possible causal mechanisms in addition to neurotoxicity, those suggested means of injury are likewise insufficiently substantiated. (*See* Sections VIII(C) and (D), *supra*.)

B. Petitioners have failed to establish Prong 2 of Althen in this case.

Under Prong 2, the Petitioners need to show that it is "more probable than not" that one of J.R.B.'s vaccinations *did* cause J.R.B.'s *own* condition. But this they have failed to do, for all of the reasons detailed above. I note in particular that Dr. Marks has failed to even specifically identify any vaccine or vaccines that he believes did cause J.R.B.'s condition. Thus, even if Petitioners had established as a general matter that some vaccines contain potentially injurious neurotoxic elements, they still would not have established that any of J.R.B.'s *own* vaccinations fit into such a category. And in any event, J.R.B.'s medical records do not support Dr. Marks' argument that J.R.B. experienced "a stepwise regression after each vaccine administration." (Ex. 11, p. 3.) This was the only basis that Dr. Marks articulated for believing that his theory was operative in J.R.B.'s case in particular. Moreover, Dr. Wiznitzer adequately rebutted Petitioners' contention that J.R.B.'s clinical history is consistent with a "regressive encephalopathy" after his vaccine administration, arguing instead that his condition is consistent with the onset of an ASD unrelated to vaccination. Thus, Petitioners have failed to establish Prong 2 of *Althen* in this case.[22]

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[22] To clarify, Petitioners have failed to show that J.R.B.'s autism was either *initially caused* by his vaccinations, or was *aggravated* in any way by his vaccinations.

In this regard, I note that where a petitioner in a causation-in-fact (or "off-Table") vaccine case is seeking to prove that a vaccination *aggravated* a pre-existing injury, in addition to the three *Althen* factors discussed herein, the factfinder ordinarily must also apply three additional factors. *See Loving v. HHS*, 86 Fed. Cl. 135, 144 (Fed. Cl. 2009)(combining the first three *Whitecotton* factors for claims regarding aggravation claims with the three *Althen* factors for causation-in-fact injury claims to create a six-part test, for causation-in-fact aggravation claims); *see also W.C. v. HHS*, 704 F.3d 1352, 1357 (Fed. Cir. 2013)(applying the six-part *Loving* test.). The additional *Loving* factors require the Petitioners to demonstrate aggravation by showing: (1) the vacinee's condition prior to the administration of the vaccine, (2) the vacinee's current condition, and (3) whether the vacinee's current condition constitutes a "significant aggravation" of the condition prior to the vaccination. (*Id*.) Although Petitioners in this case are technically advancing an "aggravation" claim, in that they assert that J.R.B.'s autism is a result of an aggravation of his mitochondrial disorder by his vaccinations, it is unnecessary to separately reach the additional *Loving* factors in this case. For the reasons discussed below, the *Althen* factors, which are themselves incorporated into the *Loving* test, decide this case on the question of *possible vaccine involvement*, without the need to determine under the complete *Loving* test whether J.R.B.'s autism actually constitutes an aggravation of his mitochondrial disorder. (In other words, whether or not his ASD constitutes an aggravation of his mitochondrial disorder, or his ASD is in any way connected to his mitochondrial disorder, is irrelevant here, because there is an complete lack of persuasive evidence that J.R.B.'s *vaccinations* played any role in causing or aggravating *either* his mitochondrial disorder *or* his ASD.)

C. Petitioners have failed to establish Prong 3 of Althen in this case.

Since I have explained why Petitioners have failed to satisfy the *first* and *second* prongs of *Althen*, I need not discuss why Petitioners' case also fails to satisfy the *third* prong. However, I note again that Dr. Marks' reliance on a "stepwise regression after each vaccine administration" is not supported by the record. Moreover, he explicitly declined to set forth any *expected* timeframe, after vaccination, in which one would expect a condition like J.R.B.'s to develop. He stated that "there are vaccines which can cause either a more rapid or a less rapid neuro toxicity, so either response is seen and documented in the medical literature. Time to injury itself does not include or exclude vaccine injury." (Ex. 11, p. 3.) Dr. Marks provided no citation for this assertion. Without further substantiation from Dr. Marks, this would preclude any finding of a proximate temporal relationship between the vaccination and the injury, as required under *Althen* Prong 3.

D. This is <u>not</u> a close case

As noted above, in *Althen* the Federal Circuit indicated that the Vaccine Act involves a "system created by Congress, in which close calls regarding causation are resolved in favor of injured claimants." 418 F.3d at 1280. Accordingly, I note here that this case ultimately is *not* a close case. For all the reasons set forth above, I found that Dr. Marks' theory was *not at all* persuasive, while Respondent's experts were *far* more persuasive.

XI

CONCLUSION

The record of this case demonstrates plainly that J.R.B. and his family have been through a tragic ordeal, and I have great sympathy for the family. However, I must decide this case not on sentiment, but by analyzing the evidence. Congress designed the Program to compensate only the families of those individuals whose injuries or deaths can be linked causally, either by a Table Injury presumption or by a preponderance of "causation-in-fact" evidence, to a listed vaccine. In this case, the evidence advanced by the Petitioners has fallen far short of demonstrating such a link. Accordingly, I conclude that the Petitioners in this case are *not* entitled to a Program award on J.R.B.'s behalf.[23]

/s/ George L. Hastings, Jr.
George L. Hastings, Jr.
Special Master

[23] In the absence of a timely-filed motion for review of this Decision, the Clerk of the Court shall enter judgment accordingly.